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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/058,566	01/28/2002	Marc C. Albertsen	1147	4729

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EXAMINER

KUBELIK, ANNE R

ART UNIT PAPER NUMBER

1638

DATE MAILED: 03/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/058,566

Applicant(s)

ALBERTSEN ET AL.

Examiner

Anne R. Kubelik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2004 and 20 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36,38,39 and 41-57 is/are pending in the application.
- 4a) Of the above claim(s) 1-34 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 38 is/are allowed.
- 6) ☒ Claim(s) 35-36, 39 and 41-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-36, 38-39 and 41-57 are pending.
2. This application contains claims 1-34 drawn to an invention nonelected with traverse in the response filed 8 October 2003. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.
3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. The oath or declaration is defective because the specification to which the oath or declaration is directed has not been adequately identified. See MPEP § 601.01(a). The objection is repeated for the reasons of record as set forth in the Office action mailed 27 February 2004. Applicant's arguments filed 13 August 2004 have been fully considered but they are not persuasive.

Applicant urges that an oath is appropriate without an identifying application number where the inventors are named and reference is made to an attached specification (response pg 10).

This is not found persuasive. The declaration lacking referring to an attached specification and filed 28 January 2002 with the original application was not signed. The signed declaration filed 15 April 2002 was not filed with an attached specification, and thus must identify the application by application number and filing date.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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5. The rejection of claims 37-38 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is withdrawn in light of Applicant's cancellation or amendment of the claims.

Claim Objections

6. Claims 39 and 52 are objected to because of the following informalities: The objection is repeated for the reasons of record as set forth in the Office action mailed 27 February 2004, as applied to claims 36, 38-39, 48-49, 51-54 and 56-57. Applicant's arguments filed 13 August 2004 have been fully considered but they are not persuasive.

Applicant urges that the changes have been adopted (response pg 11).

This is not found persuasive because the following were overlooked:

In claim 39, in line 3, "ID." should be replaced with --ID--.

In claim 52, there should be an article before "function" in line 1.

Claim Rejections - 35 USC § 112

7. Claims 35-36, 39 and 46-57 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for promoters of SEQ ID NO:5 or 6 and certain methods of their use, does not reasonably provide enablement for a multitude of nucleic acids that hybridize to SEQ ID NO:5 or that are essential for the transcription of the BS92-7 gene, and methods of their use. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is repeated for the reasons of record as

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set forth in the Office action mailed 27 February 2004, as applied to claims 35-37, 39-40 and 46-57. Applicant's arguments filed 13 August 2004 have been fully considered but they are not persuasive.

Applicant urges that the structure of the promoter is shown, both as cDNA and genomic DNA and was obtained from both maize and sorghum (response pg 11).

This is not found persuasive. The sequences as presented in the application are as follows:

SEQ ID NO:1	cDNA of maize BS92-7
SEQ ID NO:2	protein of maize BS92-7
SEQ ID NO:3	genomic DNA sequence of maize BS92-7 gene
SEQ ID NO:4	there no sequence under this sequence identifier
SEQ ID NO:5	promoter of maize BS92-7
SEQ ID NO:6	essential region of maize BS92-7 promoter
SEQ ID NO:7	partial cDNA of sorghum BS92-7
SEQ ID NO:8	partial protein of sorghum BS92-7

The sequence for the sorghum BS92-7 promoter is not present in the instant specification. It is noted that promoters are not present on cDNA sequences.

Applicant urges that the promoter's ability to drive genes in a male tissue preferential manner is demonstrated, and an essential region identified; identification of this region further adds to ability to identify the structure which provides the promoter with male tissue preferential expression (response pg 11).

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This is not found persuasive. Promoters of SEQ ID NO:5 or 6 and certain methods of their use are enabled; what is not enabled is nucleic acids that hybridize to SEQ ID NO:5 or that are essential for the transcription of the BS92-7 gene, and methods of their use.

Applicant urges that various sequences can be effective in directing expression of a gene to male tissue and they do not have to contain the 30 bp sequence of the tomato promoter in Eyal et al and that such a situation argues for the novelty and non-obviousness of the present invention (response pg 11-12).

This is not found persuasive. The enablement rejection is made because the specification does not teach male-tissue preferred promoters that hybridize to SEQ ID NO:5 and 6, and those SEQ ID NO:5 and 6 are different enough from the teachings in the art that the art cannot be used as guidance for making promoters that hybridize to SEQ ID NO:5 and 6.

Applicant does not dispute that identification of the functional parts of promoters is unpredictable, that promoters with similar expression patterns may have very different sequence elements, or that the region of a promoter with a particular activity is not predictable, and urges that the invention provided here is the structure and region (response pg 12).

This is not found persuasive. The differences between SEQ ID NO:5 and 6 and the promoters in the art that the art means that prior art promoters cannot be used as guidance for making promoters that hybridize to SEQ ID NO:5 and 6.

Applicant urges that they have taught sequences that hybridize to SEQ ID NO:5 and 6 (response pg 12-13).

⁴ This is not found persuasive because no sequences that hybridize to SEQ ID NO:5 and 6 are taught.

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8. Claims 35-36, 39 and 46-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 27 February 2004, as applied to claims 35-37, 39-40 and 46-57. Applicant's arguments filed 13 August 2004 have been fully considered but they are not persuasive.

Applicant urges that the sequences are set forth and claims follow example 9 of the written description guidelines; thus, a representative number of species is shown (response pg 13).

This is not found persuasive because example 9 of the written description guidelines is drawn to a cDNA that encodes a promoter, not to a promoter. Additionally, hybridizing sequences were isolated and shown to encode proteins with the same function as the identified sequence. In the instant case, no other promoters were isolated. Thus, a representative number of species are not presented in the specification.

Applicant urges that one of skill in the art would not expect substantial variation among species included within the claims and the hybridization conditions will yield structurally similar DNAs (response pg 13).

This is not found persuasive. The structural features of nucleic acids that hybridize to SEQ ID NO:5 or that are essential for the transcription of the BS92-7 gene have not been described.

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9. Claims 39, 51 and 55-57 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections. The rejection is modified from the rejection set forth in the Office action mailed 27 February 2004, as applied to claims 35-37, 39-40 and 46-57, due to applicant's amendment of the claims. Applicant's arguments filed 13 August 2004 have been fully considered but they are not persuasive.

Claim 56 is indefinite in their recitation of "essential for imitating transcription of the BS92-7 gene." Claim 39 is similarly indefinite in its recitation of "essential for imitating transcription of SEQ ID Nos. 1, 3 or 7." It is not clear if applicant is referring to the essential region of the promoter of the BS92-7 gene or if Applicant is referring to any promoter, which would be essential for initiating any gene. For purposes of examination, the latter interpretation was used.

Applicant did not address this rejection.

In claim 51 it is unclear what the phrase following "comprising" is intended to modify. - plant? Method? By position in the claim it modifies "plant".

Applicant urges that a comma is added after "plant" to reflect that the phrase modifies the method (response pg 14).

This is not found persuasive because the phrase follows "plant"; without reference to the method, the phrase appears to modify "plant". It is suggested that "comprising" be replaced with --wherein the method comprises--.

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Claim 51 lacks antecedent basis for the limitation “the regulatory element in conjunction with the promoter” in line 3.

Applicant urges that the claim is now dependent upon claim 47 (response pg 14).

This is not found persuasive because this still fails to provide antecedent basis for the limitation “the regulatory element in conjunction with the promoter”.

¶ Claim 55 lacks antecedent basis for the limitations “ the male sterile plant” in line 1 and “the second sequence” in line 3.

Applicant urges that the claim is now dependent upon claim 52 (response pg 14).

This is not found persuasive because this still fails to provide antecedent basis for the limitations.

Claims 56-57 provide for the production of second and fourth parent plants, respectively, but do not set forth any active, positive steps involved in the method.

Applicant urges that claim 56 recites the positive steps of producing a first plant, producing a second plant and crossing the plants, and claim 57 is amended to add that the method further comprises growing seed to produce third and fourth plants (response pg 14).

This is not found persuasive because the starting materials of these method steps are not recited.

Claim Rejections - 35 USC § 102

10. Claims 36, 39, 46-53 and 56 are rejected under 35 U.S.C. 102(b) as being anticipated by Van Tunen et al (1999, US Patent 6,005,167). The rejection is repeated for the reasons of record as set forth in the Office action mailed 27 February 2004, as applied to claims 36-37, 39, 46-53

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and 56. Applicant's arguments filed 13 August 2004 have been fully considered but they are not persuasive.

Applicant urges that there is no basis to believe that these sequence would hybridize under the conditions recited in the claim, and that SEQ ID NO:5 has only 56.25% homology with applicant's [sic] claimed sequences, which would have a T_m of 27°C for the complex (response pg 15).

This is not found persuasive. Applicant's "high stringency hybridization conditions" recite a very high salt concentration, which would greatly increase the hybridization between sequences. Applicant has not shown the sequence alignment used to generate the calculation of 56.25%.

Applicant urges that SEQ ID NO:6 has only 32.14% homology with applicant's [sic] claimed sequences, which would have a T_m of 30°C for the complex (response pg 15).

This is not found persuasive. Applicant's "high stringency hybridization conditions" recite a very high salt concentration, which would greatly increase the hybridization between sequences. Applicant has not shown the sequence alignment used to generate the calculation of 32.14%.

11. Claims 36, 39, 46-47, 49-53 and 55-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Hodges et al (1999, US Patent 5,929,307). The rejection is repeated for the reasons of record as set forth in the Office action mailed 27 February 2004, as applied to claims 36-37, 39, 46-47, 49-53 and 55-56. Applicant's arguments filed 13 August 2004 have been fully considered but they are not persuasive.

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Applicant urges that no sequence disclosed in '307 would hybridize to Applicant's claimed sequences at high stringency; no DNA:DNA duplexes could be formed in these conditions (response pg 15).

This is not found persuasive. Applicant's "high stringency hybridization conditions" recite a very high salt concentration, which would greatly increase the hybridization between sequences.

12. Claims 36, 39, 46-54 and 56-57 are rejected under 35 U.S.C. 102(b) as being anticipated by Albertsen et al (1999, US Patent 5,859,341). The rejection is repeated for the reasons of record as set forth in the Office action mailed 27 February 2004, as applied to claims 36-37, 39-40, 46-54 and 56-57. Applicant's arguments filed 13 August 2004 have been fully considered but they are not persuasive.

Applicant urges that no sequence disclosed in '341 would hybridize to Applicant's claimed sequences at high stringency; no DNA:DNA duplexes could be formed in these conditions (response pg 15).

This is not found persuasive. Applicant's "high stringency hybridization conditions" recite a very high salt concentration, which would greatly increase the hybridization between sequences.

13. Claim 38 is allowed.

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Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

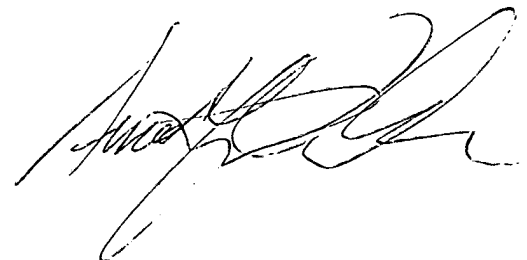
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. The central fax number for official correspondence is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Anne R. Kubelik, Ph.D.
March 9, 2005



**ANNE KUBELIK, PH.D.
PRIMARY EXAMINER**